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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,297	09/22/2003	William F. Long	15186-32US JA/LB/ld	5632
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			ART UNIT	PAPER NUMBER
			2877	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/665,297

Applicant(s)

LONG ET AL.

Examiner

Kara E Geisel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13-20, 22-27, 35 and 37-40 is/are rejected.
- 7) ☒ Claim(s) 12, 21, 28-34 and 36 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 16-17, and 39-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 recites the limitation "the biological tissue" in line 1. There is insufficient antecedent basis for this limitation in the claim.

In regards to claim 39, line 1, the preamble sets forth a system, which depends on a method claim. Was this claim supposed to depend on claim 22?

Claims, which are dependent from claim(s) 16 and 39 inherit the problems of these claim(s), and are therefore also rejected under 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 8, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Knuettel et al. (USPN 5,962,852).

In regards to claim 1, Knuettel discloses a method for collecting optical data for use in time resolved optical imaging (column 6, lines 43-56) of an animal (column 1, lines 8-17) comprising positioning said animal for data acquisition through free space optics (fig. 8), directionally propagating through the free space optics a pulsed light beam of a selected intensity

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(14; column 6, lines 43-56) to illuminate at one or more wavelengths a predetermined illumination point in a region of interest of the animal (17), selectively collecting through the free space optics, light emanating from a plurality of predetermined collection points (collection point 17; light collected 19), directionally propagating through the optics the collected light towards a detector (20a-c), measuring, at one or more wavelengths, the collected light at the detector to produce a time resolved optical signal for one or more illumination points/collection points configuration (column 6, lines 43-56), and wherein light emanating from points other than the predetermined collection points is optically excluded from detection (24; column 6, lines 1-10).

In regards to claim 8, the optical signal is detected at two or more wavelength simultaneously (column 12, lines 48-50).

In regards to claim 22, Knuettel discloses a system for collecting optical data (fig. 8) for use in time resolved optical imaging (column 6, lines 43-56) of an animal (column 1, lines 8-17) comprising one or more pulsed light sources of selected intensity (10a-c) for providing a light beam at one or more wavelengths (column 6, lines 43-56), illuminating optic components for directionally propagating the beam (14) through free space optics (45a-b, 46, 40, 41) such that a region of interest of the biological tissue is illuminated at a plurality of illumination points thereby injecting light into the animal (17), collecting optic components (24) for collecting through free space optics light re-emitted at a plurality of predetermined collection points (17) in the region of interest such that light emanating from points other than the predetermined collection points is optically excluded from detection, and for directionally propagating, through free space optics (41, 40, 46, 47a-b), the collected light (19), and a time domain detector for detecting the collected light (20a-c; column 6, lines 43-67).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-7, 18, 23-24, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knuettel et al. (USPN 5,962,852) in view of Miwa et al. (USPN 6,615,063).

In regards to claim 2, while Knuettel does not disclose what the time resolved imaging consists of, it is disclosed that any suitable means for doing time resolved measurements can be used in order to measure the concentration of an analyte in a scattering body (column 6, lines 56-67).

Miwa discloses several methods to measure the concentration of an analyte in a scattering medium such as a human body (column 1, lines 6-11). One method is time resolved optical imaging that is time domain imaging and wherein the time resolved optical signal is detected such as to generate information related to a temporal spread function (column 1, lines 13-24). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use Miwa's time domain imaging as the time resolved imaging in Knuettel's method in order to measure the concentration of an analyte in a scattering body.

In regards to claims 3 and 37, the combined method could employ time correlated single photon counting approach (TCSPC) (Miwa column 1, lines 25-30).

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In regards to claim 4, in the combined method above, each illumination point is illuminated by a plurality of pulses (Knuettel column 6, lines 43-52).

In regards to claims 5-7 and 23, the combined system does not disclose adjusting the intensity of the source with filters to avoid distortions caused by electronics dead-time losses. However, it is well known in the art of TCSPC to adjust the intensity of the source so that the probability of detecting a photon for each illumination light pulse is approximately 1% in order to avoid distortions due to electronics dead-time losses (applicant's specification ¶ 37). Furthermore, it is well known in the art that neutral density filters are suitable for this purpose (see prior art below). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust the combined system's source's intensity with a filter in order to avoid distortions caused by electronics dead-time losses.

In regards to claim 18, the TPSF would be integrated to provide attenuation measurement (Miwa column 1, lines 39-50).

In regards to claim 24, the light sources are lasers (column 12, lines 35-39).

Claims 9 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knuettel et al. (USPN 5,962,852).

In regards to claim 9, Knuettel does not disclose detecting the optical signal at two or more wavelengths sequentially. It is disclosed to measure two or more wavelengths simultaneously with multiple detectors (column 12, lines 48-50). It is very well known in the art that instead of two wavelengths being measured by different detectors simultaneously, the two wavelengths can be measured by the same detector sequentially, in order to save the cost of the extra detector. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to measure the two wavelengths of Knuettel's device sequentially, in order to save the cost of one detector.

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In regards to claims 15-17, although it is not disclosed that detection is effected at a different wavelength than that of the illumination, using fluorescence to measure the concentration of an analyte is very well known in the art, and would be obvious to one of ordinary skill in the art, in order to have a better contrast of the analyte versus interfering structures in the animal which might obscure measurement of the concentration of the analyte. Furthermore, it would be obvious, in this case, to measure both the excitation and emission wavelength, since it is also well known that the wavelength and intensity of light sources fluctuate due to temperature and aging, and the exact wavelength of the light source would need to be measured to correct for any problems this might cause.

Claims 1, 10-11, 13-14, 19-20, 22, 25-27, 35, and 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsuchiya (USPN 6,335,792) in view of Grable (USPN 6,662,042).

In regards to claims 1 and 22, Tsuchiya discloses a method and system for collecting optical data for use in time resolved optical imaging (column 11, lines 11-18) of an animal (column 1, lines 34-37) comprising positioning said animal for data acquisition through optics (fig. 2), directionally propagating through the optics a pulsed light beam of a selected intensity (23; column 26, lines 46-50) to illuminate at one or more wavelengths a predetermined illumination point in a region of interest of the animal (u1-up), selectively collecting through the optics, light emanating from a plurality of predetermined collection points (v1-vq), directionally propagating through the optics the collected light towards a detector (26), measuring, at one or more wavelengths, the collected light at the detector to produce a time resolved optical signal for one or more illumination points/collection points configuration (column 27, lines 17-31), and wherein light emanating from points other than the predetermined collection points is optically excluded from detection (column 27, lines 8-16). Tsuchiya does not disclose that free space optics are used.

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Grable discloses a similar device for use in time resolved imaging of an animal (fig. 3), wherein a light source is scanned over a plurality of illumination points (fig. 11), and wherein light emanating from a plurality of predetermined collection points is collected (fig. 11, by detectors 40). Instead of fibers directing the light to the illumination points and collection points, free space optics are used to direct the light to the illumination points and collection points. This is done so that the entire portion of the animal may be scanned with ease. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use free space optics in place of Tsuchiya's optics as an alternate embodiment and so that the entire region of interest of the animal can be scanned with ease.

In regards to claim 10, in the combined system the illumination points are illuminated in a raster scan fashion.

In regards to claim 11, the collection points are located at a fixed distance from the illumination points to provide optical signal for topographic imaging (fig. 2).

In regards to claim 13, two or more collection points are collected for each illumination point to provide optical data for tomographic imaging (columns 1-2, lines 65-67 and 1-8 respectively and column 1, lines 22-27).

In regards to claim 14, at least two of the two or more collection points are collected simultaneously (column 26, lines 54-65).

In regards to claim 19, in the combined system optical data from a plurality of regions of interest are collected during a single session (Grable column 2, lines 7-24).

In regards to claim 20, although the combined device does not scan the whole body of the animal, it is disclosed that the device could be used to measure cancerous growth in a part of the body of an animal (column 1, lines 16-25). Since tumors can grow in any part of an animal body, it would be obvious to configure this device to be able to do the same measurement over the whole body of an animal in order to determine tumor growth over the whole body.

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In regards to claims 25-26, the combined system using free space optics comprises at least one moveable mirror galvanometer for directing the beam to the plurality of illumination points (Grable column 16, lines 49-59 and fig. 28).

In regards to claim 27, the combined system using free space optics further comprises a thin angled mirror located optically downstream of the mirror galvanometer (Grable fig. 25, 318).

In regards to claim 35, in the combined system, the illuminating beam comprises a translational stage for moving in a plane perpendicular to a tray, which is used for supporting the animal (Grable fig. 2, 16 and column 2, lines 15-23). This is equivalent to the illuminating beam being held stationary, and the tray having a translational stage for moving the tray in a plane perpendicular to the illuminating beam, and it would be obvious to one of ordinary skill in the art to switch which item was moving, as an alternate embodiment of the system.

In regards to claim 38, the combined system can have any detector suitable for time resolved imaging, which would include a time gated ICCD.

In regards to claims 39-40, the combined system has a light tight enclosure (Grable fig. 3A), which contains the animal (15), the optical components (48, 38), and the detector (40).

Allowable Subject Matter

Claim 12, 21, 28-34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

As to claim 12, the prior art of record, taken alone or in combination, fails to disclose or render obvious a method for collecting optical data for use in time resolved optical imaging of an animal wherein a distance is about 3mm, in combination with the rest of the limitations of claim 12.

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As to claim 21, the prior art of record, taken alone or in combination, fails to disclose or render obvious a method for collecting optical data for use in time resolved optical imaging of an animal wherein the animal is controllably heated, in combination with the rest of the limitations of claim 21.

As to claim 28, the prior art of record, taken alone or in combination, fails to disclose or render obvious a system for collecting optical data for use in time resolved optical imaging of an animal wherein a lens is positioned between a mirror galvanometer and a thing angled mirror and optically coupled therewith to provide a telecentric imaging configuration, in combination with the rest of the limitations of claim 28.

As to claim 36, the prior art of record, taken alone or in combination, fails to disclose or render obvious a system for collecting optical data for use in time resolved optical imaging of an animal wherein a tray is controllably heated to a desired temperature suitable for the animal, in combination with the rest of the limitations of claim 36.

Additional Prior Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The prior art of record is Ntziachristos et al. (USPN 6,615,063), and Mycek et al. (US Pub 2004/0073119).

Ntziachristos discloses a method and system for collecting optical data for use in time resolved optical imaging of an animal comprising positioning said animal for data acquisition through optics, directionally propagating through the optics a pulsed light beam of a selected intensity to illuminate at one or more wavelengths a predetermined illumination point in a region of interest of the animal, selectively collecting through the optics, light emanating from a plurality of predetermined collection points, directionally propagating through the optics the collected light towards a detector, measuring, at one or more wavelengths, the collected light at the detector to produce a time resolved optical signal for one or more illumination points/collection points

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configuration, and wherein light emanating from points other than the predetermined collection points is electronically excluded from detection.


Mycek discloses a method and system for collecting optical data for use in time resolved optical imaging of an animal comprising positioning said animal for data acquisition through optics, directionally propagating through the optics a pulsed light beam of a selected intensity to illuminate at one or more wavelengths a predetermined illumination point in a region of interest of the animal, selectively collecting through the optics, light emanating from a collection point, directionally propagating through the optics the collected light towards a detector, measuring, at one or more wavelengths, the collected light at the detector to produce a time resolved optical signal for one or more illumination points/collection points configuration, and wherein light emanating from points other than the predetermined collection points is optically excluded from detection. Furthermore, a neutral density filter is used to adjust the intensity of the source so that the probability of detecting a photon for each illumination light pulse is approximately 1% in order to avoid distortions due to electronics dead-time losses.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kara E Geisel whose telephone number is **571 272 2416**. The examiner can normally be reached on Monday through Friday, 8am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory J. Toatley, Jr. can be reached on **571 272 2800 ext. 77**. The fax phone numbers for the organization where this application or proceeding is assigned are 703 872 9306 for regular communications and 703 872 9306 for After Final communications.

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F.L. Evans
Primary Examiner
Art Unit 2877

K.G.
KEG
August 23, 2004